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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,384	06/01/2001	Derek J. Hei	282172000810	5308

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EXAMINER	
MARSCHEL, ARDIN H	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,384	HEI, DEREK J.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/23/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2/13/04* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of the specie of polyaromatic resin and the specie of 4-primary amino-substituted psoralen in the Paper filed 2/23/04 is acknowledged. The traversal is on the ground(s) that the species are not directed to mutually exclusive subject matter. In response this argument is not understood because a polyaromatic resin vs. the non-elected non-polyaromatic resin is clearly completely exclusive subject matter. Applicant's argument on this point therefore is inconsistent with the factual basis for the specie description. Applicants further argue that only one specie is explicitly recited in the claims regarding the polyaromatic resin specie. This argument is also inconsistent with the facts because applicants also admitted in arguments that claim 1 is generic and must therefore include the non-elected non-polyaromatic specie, otherwise claim 5 would not be further limiting regarding the type of resin. A dependent claim such as claim 5 is required to be further limiting from a claim from which it depends. Applicants argue yet further that there is no undue search burden as applicants' representative is unaware of separate art classifications which must be searched or an inordinate body of art that would need to be reviewed. In response again this argument is inconsistent with the factual basis for the species where clearly exclusive species would entail a distinct search for each. Also, applicants' unawareness regarding separate art or a body of art does not prevent the need for a search for such art during examination. Thus these traversal arguments are not found persuasive.

Applicants also argue the second specie election drawn to psoralen species with the argument that there is no undue search burden as applicants' representative is unaware of separate art classifications which must be searched or an inordinate body of art that would need to be reviewed. In response again this argument is inconsistent with the factual basis for the species where clearly exclusive species would entail a distinct search for each for psoralen species. Also, applicants' unawareness regarding separate art or a body of art does not prevent the need for a search for such art during examination. Thus these traversal arguments are not found persuasive.

Claim 19 is therefore withdrawn from consideration at this time due to being directed to non-elected species.

The requirement is still deemed proper and is therefore made FINAL.

INFORMATION DISCLOSURE STATEMENT

On the enclosed PTO Form 1449 the Office action citations have been lined through because they do not have dates of publication as required for citations on a PTO Form 1449. These Office action, however, are hereby noted as having been considered. Applicants also disclose related application serial number 10/051,976. Said application serial number 10/051,976 is hereby acknowledged as having been considered.

SEQUENCE RULE NON-COMPLIANCE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). See page 114, lines 13-16, of the instant specification.

However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statements under 37 CFR §§ 1.821(f) and (g), and SEQ ID Nos cited along with each sequence in the specification or Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

VAGUENESS AND INDEFINITENESS

Claims 1-18 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 1-2, cites the method of "treating a blood product which contains a nucleic acid-containing pathogen to be inactivated". This may be interpreted as directing the claimed method therein to inactivation of the cited pathogen. Confusingly, nothing in the actual claim steps are directed to such inactivation but merely only to adding psoralen with irradiation to form a mixture followed by resin contacting practice. Although such steps may or may not inactivate such a pathogen, the claim steps do not

clearly and concisely practice these steps for such inactivation. For example, the irradiation is not cited as being sufficient in intensity for such inactivation, nor that the amount of psoralen photoproduct is sufficient for such inactivation. Therefore the claim is vague and indefinite as to whether the preamble or the actual claim steps control the metes and bounds of the claim. Claims which depend directly or indirectly from claim 1 are also rejected hereinunder due to their dependence. Clarification of the metes and bounds of said claims is requested via clearer claim wording.

Claim 8 is vague and indefinite as to what is meant regarding removal of free psoralen. In one interpretation the resin contacting step may be interpreted as being specific for free psoralen removal with leaving the nucleic acid bound psoralen yet in the biological fluid. Another conflicting interpretation is that the recitation of free psoralen does not limit the resin contacting practice to such limited and specific free psoralen removal but rather that all psoralen whether free or bound to nucleic acid is removed thus removing substantially all free psoralen, however, with other forms of psoralen and possibly even other biological fluid contents. Clarification of the metes and bounds of claim 8 via clearer claim wording is requested. Claims which depend directly or indirectly from claim 8 are also rejected hereinunder due to their dependence.

LACK OF SCOPE OF ENABLEMENT

Claims 1-18 and 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for effective irradiating conditions which either inactivate pathogens in a blood product or biological fluid, does not reasonably provide enablement for unlimited irradiating conditions as presently claimed. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

It is firstly noted that the instant claims lack any limitation directed to what irradiating conditions are utilized to result either in pathogen inactivation or even the production of photoproducts of psoralen. In contrast, the specification on page 5 cites particular wavelengths to be utilized for irradiation, an intensity range of irradiation, exposure time periods, and a compound concentration range. Device 1 is cited in Example 15 on page 141 of the specification regarding irradiation that leads to photoinactivation. On page 166 of the specification a concern is expressed and

measured regarding platelet count maintenance during irradiation apparently to result in psoralen inactivation without damaging important blood product contents. Thus, without some limitation as to irradiation conditions the instant method either will be ineffective or undesireably damage the blood product. Without further limitation the results of irradiation are unpredictable thus supporting this rejection.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

May 14, 2004

Ardin H. Marschel 5/14/04